K072706

OCT 2 4 2007

510(k) SUMMARY

MicroPower®, MicroPower® OralMax, and MicroChoice® Handpiece Systems

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Linvatec is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) Number _____.

A. Submitter

ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

B. Company Contact

Sue F. Dauterman
Regulatory Affairs Specialist
(727) 399-5321 Telephone
(727) 399-5264 FAX

C. Device Name

Common Name: Surgical Drill System

Proposed Class/Device: Class II

Trade Name	Classification Panel	Classification Name	Product Code
MicroChoice Drills and Saws	Orthopedic	Arthroscope, 888.1100	HRX
MicroPower Drills and Saws	Neurology	Electric cranial drill motor, 882.4360	HBC
MicroPower OralMax High Speed Drill	Dental	Bone cutting instrument and accessories, 872.4120	DZI

D. Predicate/Legally Marketed Devices

510(k) Name	510(k) #	Owner
Universal Drive System	K971059	Linvatec Corporation
MicroPower Hand Piece: Medium Speed Drill, Sagittal Saw, Reciprocating Saw, and Oscillating Saw	K060198	Linvatec Corporation
MicroPower Hand Piece:High Speed Drill	K060260	Linvatec Corporation
MicroPower Hand Piece:Oral Max High Speed Drill	K060270	Linvatec Corporation

E. Device Description

The *MicroPower®, MicroPower® OralMax, and MicroChoice® Handpiece Systems* are electric pencil grip handhelds that are used in conjunction with the Advantage®, E9000® and PowerPro® controllers. A cord connects the handpiece to the controller that supplies power to the device. The handpieces have a lever or footswitch that is used to actuate the device. The drills use a wide variety of attachments, including bur guards, drill bits and burs. The saws use a wide variety of blades.

F. Intended Use

Name	Intended Use
MicroPower® Handpiece System	The *MicroPower® Handpiece System* functions as a powered instrument system consisting of drills, saws and associated handpieces to perform cutting of soft tissue and bone. The fields of application include: orthopedic, arthroscopic, neurosurgical, otolaryngological, plastic/reconstructive, and oral/maxillofacial procedures.

Name	Intended Use
MicroPower® OralMax Handpiece System	The *MicroPower® OralMax Handpiece System* functions as a powered instrument system consisting of drills, saws and associated handpieces to perform cutting of soft tissue and bone. The field of application includes only oral/maxillofacial.
MicroChoice® Handpiece System	The *MicroChoice® Handpiece System* functions as a powered instrument system consisting of drills, saws and associated handpieces to perform cutting of soft tissue and bone. The fields of application include: orthopedic, arthroscopic, otolaryngological, oral/maxillofacial, hand, foot, neuro, and plastic/reconstructive surgical procedures.

G. Technological Characteristics

The *MicroPower®, MicroPower® OralMax, and MicroChoice® Handpiece Systems* are identical to the predicate devices cleared in the original submissions except for an update to the handpiece identification mechanism as detailed in Section 9 of this submission. These modifications do not affect the device's intended use or performance specifications in a manner that raises any new issues regarding safety and effectiveness.

H. Substantial Equivalence

The *MicroPower®, MicroPower® OralMax, and MicroChoice® Handpiece Systems* are substantially equivalent in intended use, design and technological characteristics to the below listed systems.

Proposed Name	Predicate 510(k) Name	510(k) #
MicroChoice® Handpiece System	Universal Drive System	K971059
MicroPower® Handpiece System	MicroPower Hand Piece: Medium Speed Drill, Sagittal Saw, Reciprocating Saw, and Oscillating Saw	K060198
	MicroPower Hand Piece:High Speed Drill	K060260
MicroPower® OralMax Handpiece System	MicroPower Hand Piece:Oral Max High Speed Drill	K060270

Testing conducted prior to product release assures that the new devices do not raise any new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2007

ConMed Livatec
% Ms. Sue F. Dauterman
Regulatory Affairs Specialist
11311 Concept Boulevard
Largo, Florida 33773-4908

Re: K072706
Trade/Device Name: *MicroPower® Handpiece System*
MicroPower® OralMax Handpiece System
MicroChoice® Handpiece System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: September 21, 2007
Received: September 24, 2007

Dear Ms. Dauterman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

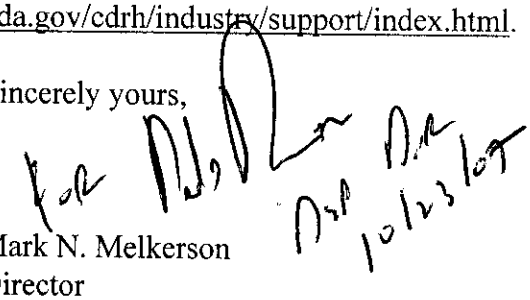
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K072706

Device Name: *MicroPower® Handpiece System*

Indications for Use:

The *MicroPower® Handpiece System* functions as a powered instrument system consisting of drills, saws and associated handpieces to perform cutting of soft tissue and bone. The fields of application include: orthopedic, arthroscopic, neurosurgical, otolaryngological, plastic/reconstructive, and oral/maxillofacial procedures.

Prescription Use X AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K072706

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

DZD D.M
10/24/07

510(k) Number K072706

510(k) Number (if known): K072706

Device Name: *MicroPower® OralMax Handpiece System*

Indications for Use:

The *MicroPower® OralMax Handpiece System* functions as a powered instrument system consisting of drills, saws and associated handpieces to perform cutting of soft tissue and bone. The field of application includes only oral/maxillofacial.

Prescription Use X AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE If NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number (if known): K072706

Device Name: *MicroChoice® Handpiece System*

Indications for Use:

The *MicroChoice® Handpiece System* functions as a powered instrument system consisting of drills, saws and associated handpieces to perform cutting of soft tissue and bone. The fields of application include: orthopedic, arthroscopic, otolaryngological, oral/maxillofacial, hand, foot, neuro, and plastic/reconstructive surgical procedures.

Prescription Use X AND/OR Over-the-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE If NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072706